

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 12 JUL 2005

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Applicant's or agent's file reference Bp 108996/JS/BK	FOR FURTHER ACTION <small>See Form PCT/PEA/416</small>	
International application No. PCT/FI2004/000226	International filing date (day/month/year) 13.04.2004	Priority date (day/month/year) 10.04.2003
International Patent Classification (IPC) or national classification and IPC A23L1/30, C11C3/00, C11C3/08, C11C3/10		
Applicant RAISIO BENECOL OY		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application 		
Date of submission of the demand 10.02.2005	Date of completion of this report 13.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Tallgren, A Telephone No. +31 70 340-3933 	

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-21 as originally filed

Claims, Numbers

1-29 as originally filed

Drawings, Sheets

1 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-29
	No: Claims	
Inventive step (IS)	Yes: Claims	1-19
	No: Claims	20-29
Industrial applicability (IA)	Yes: Claims	1-29
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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The communication from the applicant dated 10.2.2005 has been taken into consideration while drafting this IPER.

ITEM V

1. NOVEL AND INVENTIVE CLAIMS

D1 describes a method for the production of a sterol fatty acid ester rich composition (98 % purity) comprising the steps: 1) combining sterols, fatty acid (esters or fatty acid alkyl esters) and esterification catalyst with hydrolysis component to produce fatty acid sterol esters and fatty acid alkyl ester 2) Purification of sterol fatty acid ester by bleaching, filtration deodorization and distillation from catalysts, formed products (glycerol and other fatty acids) (claim 11,12,16, examples 2-6, page 7 line 22- page 15 line 24). The reaction does not contain fatty acid glycerides as first step reactant.

D2 describes a method for the production of a sterol fatty acid ester rich composition comprising the steps: 1) combining sterols, fatty acid esters and esterification catalyst with hydrolysis component to produce fatty acid sterol esters 2) Purification of sterol fatty acid ester by bleaching, filtration deodorization and distillation from catalysts, formed products (glycerol and other fatty acids) (claim 18, example 1, page 4 line 21- page 5 line 19). The reaction does not contain fatty acid glycerides as first step reactant.

Claim 1 differs from D1-D2 in that claim 1 requires combining a sterol, fatty acid glyceride and an esterification catalyst for producing sterol fatty acid esters. D1-D2 use conventional fatty acid methyl esters (no fatty acid glycerides). There is no document cited in the search report to suggest the use of fatty acid glycerides as first step reactant. Therefore a skilled person would not have a hint to come to the solution applied in this application claim 1. Consequently the claim 1 (and dependent claims 2-16) is found novel and inventive (Art 33 (2) and (3) PCT).

This new and inventive process relates to the efficiency of the process itself. A further difference is, that the process uses hydrolysis catalysts and the end product is purer and has very high yield. The by-products and catalysts are also separated efficiently. The end product differs from D1-D2 by the use of different fatty acids and process steps and

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ends up to a different end product. Consequently, the subject matter of claims 17 and 18 is found novel and inventive (Art 33 (2) and (3) PCT) as well.

3. INVENTIVE STEP OBJECTIONS

D5 describes a method for recovering sterol fatty acid esters comprising 1) adding a hydrolysis (methanol) and an alkylating component (KOH) to the mixture of sterol fatty acid ester (sterols, sterol esters, sterol fatty acid esters) and fatty acid glycerides to produce fatty acid alkyl ester without significant hydrolysis of the sterol fatty acid ester 2) removing excess alkylating and hydrolysis component and glycerol by washing with acid or adsorbent treatment 3) separating fatty acid alkyl esters from sterol fatty acid ester by deodorisation- distillation including washing steps. The sterol ester may further be reacted to sterol esters in a second separate step (example 2), but this is clearly not obligatory (page 7 lines 15-21, page 9 lines 1-7). A skilled person would consider the process of D5 without additional reaction to sterols and end up to the process suggested in claim 19 (see also claims 1,5-8,16, examples 1,2, page 5 line 19- page 6 line 17, page 7 line 15- page 8 line 32, page 9 lines 8-21, page 10 lines 25-28). Consequently, the subject matter of claims 19 and 29 is considered as being not inventive in view of D5 (Art 33 (3) PCT).

Dependent claims 20-28 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, the reasons being as follows:

The features of dependent claims 20-28 have already been employed for the same purpose (see document D5 (D3, D4)). It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect. Consequently, the subject matter of claims 20-28 is considered as being not inventive in view of D3-D5 (Art 33(3) PCT).